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| 10/524,065 | 02/08/2005 | Takaya Sugawara | KPO-TSC-P1/TK-80/US | 4447 |
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| OSTRAGER CHONG FLAHERTY & BROITMAN PC 570 LEXINGTON AVENUE FLOOR 17 NEW YORK, NY 10022-6894 | | | EXAMINER MERCIER, MELISSA S | |
| | | | ART UNIT 1615 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/524,065 | Applicant(s) SUGAWARA ET AL. | |
| | Examiner MELISSA S. MERCIER | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on May 7, 2010 is acknowledged. Claims 8-15 are now pending in this application.

Withdrawn Rejections/Objections

Claim Objections

The objection to claim 9 because of the following informalities: claims 10-11 are already limited to an acrylic pressure sensitive adhesive has been withdrawn in view of Applicants amendment to the claim as suggested by the Examiner.

The objection to claims 10-11 because of the following informalities: claims 10-11 recite "wherein the adhesive layer further comprises..." has been withdrawn in view of Applicants amendment to the claims to remove the term "further" as suggested by Applicant.

Claim Rejections - 35 USC § 103

The rejection of claims 9-10 under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. (US 6,177,098) in view of Akemi et al. (US 5,242,951) has been withdrawn in view of Applicants amendment to the independent claim to recite the orientation of the laminate layers.

The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. in view of Akemi et al. and further in view of Radloff et al. (WO

Art Unit: 1615

2002/038134) has been withdrawn in view of Applicants amendment to the independent claim to recite the orientation of the laminate layers.

The rejection of claims 9 and 11 under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 5,693,335) in view of Hoffmann et al. (US 5,393,529) and further in view of Muraoka et al. (US 5,876,745) has been withdrawn in view of Applicants amendment to the independent claim to recite the orientation of the laminate layers.

The rejection of claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. in view of Hoffmann et al. and further in view of Muraoka et al. and further in view of Radloff et al. has been withdrawn in view of Applicants amendment to the independent claim to recite the orientation of the laminate layers.

Newly Applied Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-10, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. (US Patent 4,573,996) in view of. Kawaji et al. (US 6,177,098) and further in view of Akemi et al. (US 5,242,951).

Kawaji discloses an external patch comprising a backing and a pressure-sensitive adhesive layer, wherein the backing is a laminate structure comprising a

Art Unit: 1615

polyethylene terephthalate film and a non-woven fabric (col. 3, lines 25-33, 52-54).

Kawaji further discloses the polyethylene terephthalate film has a thickness of 1.6 - 6.0 um (col. 3, lines 48-55). Kawaji further discloses the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive comprising 2-ethylhexyl acrylate, estradiol, crotonol and oleic acid (example 2) in the claimed ranges.

While Kawaji discloses using isocyanate-based cross linking agents (col. 4, lines 52-53), he fails to expressly disclose the content amount of the isocyanate-based cross linking agent. Additionally, Kawaji fails to expressly disclose the specific thickness of the non-woven fabric, however discloses the non-woven fabric has an appropriate thickness (col. 3, lines 27-33). Kawaji also does not disclose the same orientation of the backing layer laminate.

Kwiatkowska discloses a device for the administration of an active agent to the skin or mucosa (title). Applicants attention is directed to the Figures in the reference which discloses numerous embodiments. In particular, the backing layer (12) which can be a laminate of two or more films, such as polyethylene terephthalate/polyethylene or a polyethylene/metalized polyethylene terephthalate/polyethylene laminate (column 7, lines 1-5). The active agent permeable adhesive layer (16) is preferably a pressure sensitive adhesive comprising an acrylic or methacrylic resin (column 7, lines 50-55).

Akemi teaches using 0.01-2% of an isocyanate-based cross linking agent (col. 5, lines 17-18, 33-35), and more specifically in Example 3, 0.2% of an isocyanate-based cross linking agent.

Art Unit: 1615

It would have been obvious to one of ordinary skill in the art to modify the amount of cross linking agent used in order to provide the desired aging time of the pressure-sensitive adhesive layer (col. 5, lines 30-32). Akemi also teaches a backing having a laminate structure comprising a polyester film having a thickness of 1-25 um and a porous film having a thickness of 1-200 um (col. 2, lines 54-65).

It would have been obvious to one of ordinary skill in the art to modify the thickness of the non-woven fabric in order to prevent diffusion of the drug and maintain good handling properties, as desired (Kawaji: col. 3, lines 27-33). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the laminate layer orientation disclosed by Kwiatek since he discloses it is preferable to employ the flexible outer surface because it conforms to the shape of the body member to which the device is attached (column 6, lines 58-62). Kwiatek additionally discloses the material used for the outer surface layer and the backing member depends on the properties of the materials in contact with it since the primary purpose is to prevent seepage of the active agents through the outer surface of the device (column 6, lines 27-35).

Claim 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. (US Patent 4,573,996) in view of Kawaji et al. (US 6,177,098) and Akemi

Art Unit: 1615

et al. (US 5,242,951 and further in view of Radloff et al. (WO 2002/038134). US 2004/0091521 will be used herein as an English equivalent translation of WO 2002/038134.

The combination of Kwiatek, Kawaji and Akemi are discussed above and applied in the same manner.

The combination however, fails to disclose the flexible polymer film being a low density polyethylene.

Radloff et al. discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low density polyethylene [0060]. It would have been obvious to one of ordinary skill in the art to modify the materials of the backing of Akemi et al. to be that of Radloff et al. in order to provide the desired barrier effect and elasticity/flexibility [0054]-[0058], [0060].

Claims 9,11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 5,693,335) in view of Kwiatek et al. (US Patent 4,573,996) and further in view of Muraoka et al. (US 5,876,745).

Xia discloses an external patch comprising a backing and a pressure-sensitive adhesive layer, wherein the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive containing a cross linking agent, 0.5-10% by weight of isopropyl myristate as a distribution coefficient control agent (skin permeation enhancer) and 0.2-6% of norethindrone (equivalent to norethisterone) as an active ingredient (col. 2, lines 17-27, 34-59; col. 3, lines 28-30, 39-50), therefore the content amount of the

Art Unit: 1615

ingredients can fall in the claimed range. Xia also discloses examples of the cross linking agents used.

Xia further discloses the backing is a laminate structure comprising one or more polymer layers and metal foil, wherein the polymer is polyethylene terephthalate (col. 3, lines 39-50), however fails to expressly disclose the polyethylene terephthalate film having a thickness of 0.1-10 um and the inclusion of a flexible polymer film or a woven or nonwoven fabric having a thickness of 1-200 um.

However, Xia fails to expressly disclose the amount of cross linking agent used. Xia also does not disclose the same orientation of the backing layers.

The teachings of Kwiatek's backing layers are discussed above and applied in the same manner.

Muraoka teaches it is well known to utilize 0.35% of an isocyanate- based cross linking agent (Examples 2 and 8).

It would have been obvious to one of ordinary skill in the art to modify the cross linking agent to be isocyanate-based in order to provide the desired reactivity and handling properties (col. 5, lines 1-25).

Muraoka et al. discloses an external patch with a backing (support) having a laminate structure comprising a polyester film having a thickness of 0.1-10 um and a woven or nonwoven fabric having a thickness of 1-200 um (col. 6, lines 25-66). It would have been obvious to one of ordinary skill in the art utilize the laminate structure of Muraoka et al. in order to provide an improved anchoring effect (col. 7, lines 39-47; col. 1, line 58 - col. 2, line 5).

Art Unit: 1615

With respect to claim 9 the modified Xia et al. discloses the acrylic pressure-sensitive adhesive comprises 2-ethylhexyl acrylate (col. 2, line 41).

It would have been obvious to one of ordinary skill in the art to modify the quantity for each ingredient in order to optimize the desired medicinal benefits. Further, it has been held that discovering an optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. in view of Kwiatek et al. and Muraoka et al. and further in view of Radloff et al.

The combination of Xia, Kwiatek and Muraoka is discussed above and applied in the same manner.

The combination does not disclose the flexible polymer film being a low density polyethylene.

Radloff discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low density polyethylene [0060].

It would have been obvious to one of ordinary skill in the art to modify the polyethylene materials of the backing of Kwiatek to be that of Radloff in order to provide the desired barrier effect and elasticity/flexibility [0054]-[0058], [0060].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

Art Unit: 1615

(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615